

B. Braun Medical AG
Seesatz 17
6204 Sempach
Switzerland

DECLARATION OF CONFORMITY

Product Category: Sterile urinary catheter irrigation solutions

Product (Name, Type)	Size	Date of CE marking ¹ / Batch No.	Remarks
Uro-Tainer® NaCl 0.9%	50 ml	09.09.2010	
	100 ml	09.09.2010	
Uro-Tainer® M NaCl 0.9%	50 ml	09.09.2010	
	100 ml	09.09.2010	
Uro-Tainer® Suby G	50 ml	09.09.2010	
	100 ml	09.09.2010	
Uro-Tainer® Twin Suby G	60 ml	09.09.2010	
Uro-Tainer® Solutio R	50 ml	09.09.2010	
	100 ml	09.09.2010	
Uro-Tainer® Twin Solutio R	60 ml	09.09.2010	

¹Date of first production under responsibility of B. Braun Medical AG, Seesatz 17, CH-6204 Sempach.

Article numbers: see attachment

Conformity Assessment Procedure	acc. to ANNEX II excluding (4) of the COUNCIL DIRECTIVE 93/42/EEC
Classification	according to ANNEX IX of the COUNCIL DIRECTIVE 93/42/EEC
Class / Rule	Class IIa / Rule 5
Applied Standards	EN ISO 13485:2016, Certificate No. Q5 061585 0030
EC Certificates	No. G1 061585 0032; valid until 17.05.2024
Notified Body	TÜV SÜD Product Service GmbH, Ridlerstrasse 65, 80339 München, Germany
Identification no.	0123

We herewith declare under our sole responsibility that the above mentioned products meet all the provisions of the COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices as amended by Directive 2007/47/EC, which apply to them, as stated in ANNEX II excluding (4).

Sempach, 05.08.2019

B. Braun Medical AG

Peter Egli
Head of Quality Unit CoE Infection Control

Dr. Michael Gluschke
Director Global Regulatory Affairs OPM

Effective

DECLARATION OF CONFORMITY
Attachment for Medical Devices Class IIa

Art. No.	Product Name	Remarks
FB 99849	Uro-Tainer® NaCl 0.9% (10 x 50 ml)	
FB 99881	Uro-Tainer® NaCl 0.9% (60 x 50 ml)	
FB 99833	Uro-Tainer® NaCl 0.9% (10 x 100 ml)	
FB 99882	Uro-Tainer® NaCl 0.9% (60 x 100 ml)	
FB 99854	Uro-Tainer® M NaCl 0.9% (10 x 50 ml)	
FB 99853	Uro-Tainer® M NaCl 0.9% (10 x 100 ml)	
FB 99851	Uro-Tainer® Suby G (10 x 50 ml)	
FB 99839	Uro-Tainer® Suby G (10 x 100 ml)	
FB 99867	Uro-Tainer® Suby G (60 x 100 ml)	
9746609	Uro-Tainer® Twin Suby G (10 x 60 ml)	
FB 99843	Uro-Tainer® Solutio R (10 x 50 ml)	
FB 99841	Uro-Tainer® Solutio R (10 x 100 ml)	
FB 99893	Uro-Tainer® Solutio R (60 x 50 ml)	
FB 99894	Uro-Tainer® Solutio R (60 x 100 ml)	
9746625	Uro-Tainer® Twin Solutio R (10 x 60 ml)	